

**SUMMARY OF THE
ACCREDITING AUTHORITY REVIEW BOARD MEETING
JULY 11, 2002**

The Accrediting Authority Review Board (AARB) of the National Laboratory Accreditation Conference (NELAC) met on Thursday, July 11, 2002, at 8:00 a.m., Eastern Daylight Time (EDT) as part of the Eighth Annual NELAC Meeting in Tampa, Florida. The meeting was led by Ms. Judy Duncan of the Oklahoma Department of Environmental Quality. A list of action items is given in Attachment A. The list of participants is given in Attachment B. The purpose of the meeting was to cover issues in the published agenda.

WELCOME AND INTRODUCTION

Ms. Duncan introduced herself as the Chairperson of the AARB and welcomed the participants. The Committee members then introduced themselves.

AARB ANNUAL REPORT

Ms. Duncan presented a report found in attachment C. The report includes copies of the Annual Report, policy and procedures that the AARB has been developing, recommendations that have been presented, and the Charter of the AARB.

AARB QUALITY SYSTEM

Carl Kircher, Florida Department of Health, presented a report regarding the Quality System and Quality Manual for the AARB, which may be observed in Attachment D. The report describes the functions and operations of the AARB in performing its annual assessment of NELAP. Modifications have been proposed concerning language changes to this document. The structure of this document is patterned after the ISO Guide 61, which accredits the Accrediting Authorities.

Ms. Duncan noted that reviews performed to date have been of documentation regarding NELAP's consistency in following the NELAC Standards as they review Accrediting Authorities. This year the review has been delayed due to an extension granted to the Accrediting Authorities for their renewal process. The AARB is also planning a visit to the NELAC offices in Las Vegas to review the recently established central record keeping process.

EXTENSIONS GRANTED FOR RENEWALS

An explanation of the extension granted to the Accrediting Authorities, as well as the AARB's recommendation to the NELAP Director concerning timelines, may be viewed on Page 5 of Attachment C.

ASSESSMENT OF THE NELAP PROCESS

NELAP approved one new Accrediting Authority this year, the Louisiana Department of Environmental Quality. The AARB's assessment of the NELAP Accrediting Authorities recognition process may be viewed on Page 4 of Attachment C.

The assessment of the NELAP Accrediting Authorities renewal process was not available at this time due to the extension granted to the Accrediting Authorities. An attendee presented a proposal that the AARB should send out questionnaires, after a review, to the Accrediting Authorities for feedback concerning improvements that may help the review process. Everyone felt that this was an excellent proposal and that the Committee would discuss it further.

NELAC STANDARD CHANGES AND AARB

The AARB recommended to the NELAC Director that timelines for accreditation and accreditation renewals should be evaluated and that more realistic timelines need to be set. They also recommended that changes be made to Chapter 6, regarding conflict of interest between members of the NELAC evaluator team and the accrediting authority being evaluated. Chapter 6 is proposing additions to section 6.9.1 concerning this issue.

During the past year the AARB made minor revisions to the Charter. They decided that instead of permanent documents residing with various members of the AARB, they would reside in one place. Permanent files will be maintained in Las Vegas, making them more retrievable.

This coming year the AARB is planning to complete the review of the NELAP program using the new Quality System, complete a review and comparison of the renewal process, review new Accrediting Authorities, hear any appeals, continue to review the NELAC Standards, and report on how the review was accomplished.

ADJOURNMENT

There being no further business to discuss, the meeting was adjourned.

ACTION ITEMS
ACCREDITING AUTHORITY REVIEW BOARD MEETING
JULY 11, 2002

Item No.	Action	Date to be Completed
1.	Complete the review of the NELAP program using the new Quality System.	Open
2.	Complete a review and comparison of the renewal process for Accrediting Authorities.	Open
3.	Review any new Accrediting Authorities.	Open
4.	Continue to review the NELAC Standards and report on how the review was accomplished.	Open

**PARTICIPANTS
ACCREDITING AUTHORITY REVIEW BOARD MEETING
JULY 11, 2002**

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ACCREDITING AUTHORITY REVIEW BOARD (AARB)

Annual Report and Functions

July 2002

ACCREDITING AUTHORITY REVIEW BOARD (AARB)
Annual Report and Functions

Table of Contents

A. AARB General Operations	3
Business Meetings	3
AARB Annual Meeting and Election of Chair and Secretary	3
Document Control System for AARB	4
Development of AARB Quality System.....	4
Follow-up on Previous AARB Recommendations	4
B. Appeals	4
C. Monitoring of NELAP	4
AARB Assessment of NELAP Accrediting Authority Recognition Process	4
AARB Assessment of NELAP Accrediting Authority Renewal Process.....	5
Review of NELAP SOPs and Documents	5
Policies and Procedures	6
A. AARB General Operations	6
Revision of Charter	6
Business meetings.....	6
AARB Annual meeting election of Chair and Secretary	6
Document control system for the AARB Documents.....	6
B. Appeals	6
AARB Appeal Board Functions.....	6
Review of a portion of On-site Assessment Reports of Accrediting Authorities	7
Review of NELAP Internal Audit.....	8
ATTACHMENT B	9
Revocation Procedure	9
Recommendations from 2001	9
AARB Comments NELAP’S 2001 Documents	9
ATTACHMENT C	10

Introduction to the Report of the Accrediting Authority Review Board

At the beginning of the third year of the Accrediting Authority Review Board (AARB) a list of Future Plans of Action was developed for use in guiding AARB activities. This list included the following.

1. Review NELAC standards to see where AARB was mentioned and compare to the Charter.
2. Audit NELAP performance for the two-year Accrediting Authority (AA) renewal cycle.
3. Review Standard Operating Procedures (SOPs) developed for and by NELAP.
4. Track progress of NELAP development of a records retention policy and its implementation.
5. Audit the NELAP process for approval of any new AAs.
6. Review time frames for AA approval and renewals.
7. Handle any appeals to the AARB.

A review of AARB activities will show that all seven items were addressed.

In preparing this AARB Annual Report, we have prepared consolidated listings of Policies and Procedures adopted by the AARB (Attachment A) and a summary of past AARB recommendations to the NELAP Director and NELAC Board of Directors (Attachment B).

AARB Annual Report and Functions

A. AARB General Operations

Revision of the Charter

Prior to reviewing the AARB Charter, AARB reviewed NELAC standards to determine if changes to the standards necessitated changes to the Charter and determined that none did. The AARB recommended to the NELAP Director that the language in the Section 3, Duties and Scope of Activities, be revised to reflect that the AARB conducts annual “review” or the NELAP process for recognizing AAs rather than “audits” of this process. The revised language of the Charter is included in this report as Attachment C.

Business Meetings

The AARB met at the NELAC 7 and 7i meetings and conducted a number of conference call meetings. As included in the AARB Policy and Procedure for Business Meetings, the NELAP Director was consulted on recommended changes to the Charter and on other items of business during the year.

AARB Annual Meeting and Election of Chair and Secretary

At present, the AARB members and officers include the following:

George Mills, Term end 2002
Judy Duncan, Chair, Term end 2003
Carol Madding, Secretary, Term end 2004
Carl Kircher, Term end 2005
Dan Hickman, Term end 2006

Document Control System for AARB

The Document Control Policy and Procedure for AARB was revised to reflect that the permanent files for AARB would be maintained with the permanent files for NELAP.

Development of AARB Quality System

After seeking input from attendees at the NELAC 7i AARB session, Dr. Carl Kircher of the AARB prepared a draft AARB Quality System based upon ISO 61. This draft system has been reviewed by AARB and will be presented for discussion and input at the AARB session of the NELAC 8 meeting.

Follow-up on Previous AARB Recommendations

In the AARB 2000 Annual Report a recommendation was made that the NELAP program should document that there were no conflict of interest issues between individuals chosen to serve on a NELAP Evaluation Team and the Accrediting Authority that was to be reviewed. In order to facilitate implementation of this recommendation, AARB reviewed Chapter 6 and determined that conflicts of interest were addressed for AAs and the laboratories that they audit but were not addressed for NELAP staff and the AAs that they audit. AARB recommended the following language to the Chapter 6, Accrediting Authority, Committee to address this issue:

6.9.1 NELAP Evaluation Team

...
(e) The NELAP evaluation team shall:

- ...
- (3) Be free from conflict of interest that would compromise acting in impartial nondiscriminatory manners.
 - (4) ~~(3)~~ All experience required...

B. Appeals

No NELAP decisions were appealed to the AARB during the time period covered by this report.

C. Monitoring of NELAP

AARB Assessment of NELAP Accrediting Authority Recognition Process

The On-Site Assessment Report for the Louisiana Department of Environmental Quality was reviewed by AARB using the procedure established for earlier reviews (see Attachment A). The AARB found that there was sufficient documentation to perform this review and that the documentation was comparable to previous On-Site Assessment documentation. This NELAP assessment held to the established time frames for completion somewhat better than past initial assessments. As was the case in past reviews, the AARB found that the narrative that accompanies the check sheet for the On-Site Assessment should be more descriptive in order to facilitate a determination that On-Site Assessments are conducted to the same level of detail. For example, rather than simply stating that a check sheet item was met, the Assessment Team should describe how the item was met or cite the AA reference for where it was met (i.e., SOP 24, Section 1, Paragraph 2).

AARB Review of NELAP Requests to Extend Time for Accrediting Authority Renewal Process
This was an interim year for Accrediting Authorities to be reevaluated. Upon approval of the AARB, extensions of the renewal process may be granted. NELAP requested extensions of the time periods for completion of the renewal process for eight EPA Regions that conducted these reviews. Since this was the first round of renewals and the process was new to all participants, AARB adopted a liberal policy for granting each of these extensions. However, members of the AARB felt that we were put in a rubber stamp position and, while the overall problem was apparent, we did not always have sufficient criteria for granting each request individually. The AARB suggests that the role of AARB in granting time extensions be reviewed to determine if this is the appropriate body or if this function should rest with the NELAP Director.

AARB Assessment of NELAP Accrediting Authority Renewal Process
AARB was unable to review the NELAP Accrediting Authority Renewal Process because extensions were granted and the process was not completed in time for files to be consolidated and transmitted to AARB with sufficient time to accomplish this review before NELAC 8.

Review of NELAP SOPs and Documents
One of the AARB findings in the first report was that documentation was difficult to find since files were kept in the EPA Regions. The AARB recommended that all documentation be forwarded and kept in one place and Las Vegas, NV was chosen by NELAP. The AARB and NELAP Director discussed the need for an AARB on-site audit of NELAP files and the problem with funding for such an activity. Near the end of the year the NELAP Director advised AARB that this funding would be available. AARB will schedule an audit when the NELAP Director advises that consolidation of files has been completed.

No new NELAP SOPs or document formats were presented to AARB for review.

AARB Recommendation Concerning Time Lines for Accrediting Authority Review and Renewal Processes

The AARB has observed that there is a recurring problem with NELAP completing Accrediting Authority reviews and renewals within the time lines specified by the NELAC standards. This problem may be due in part to first time implementation of these processes. However, AARB believes that the timelines may not be realistic for the NELAP process, which involves Regional staff as reviewers. This comment is not intended as a criticism of that process, but merely as an acknowledgement that Regional staff may have many other duties in addition to NELAP reviews. AARB has recommended to the NELAP Director that timelines for AA review and renewal review be revisited and that recommendations regarding more realistic timelines be sought from AA states, EPA Regional staff involved in NELAP reviews and the ELAB. AARB believes that the NELAP process would have more integrity if timelines were realistic and could then be expected to be more rigidly observed.

ATTACHMENT A

ACCREDITING AUTHORITY REVIEW BOARD (AARB) Policies and Procedures June 2002

A. AARB General Operations

Revision of Charter

1. Review and propose changes due to changes in Chapter 1 of the NELAC Standards
2. Review and propose changes due to recommendations from the NELAP Director
3. Review proposed changes from other interested parties
4. Recommend changes, finalize and prepare for NELAP Director's approval

Business meetings

1. Annual and Interim
2. Conference calling
3. Meet with the NELAP Director at least twice for direction and updates
 - a. Seek from Director, NELAC standard changes which may affect AARB
 - b. Future changes in AARB duties
 - c. Open meetings schedule
 - d. Role of AARB communicated to NELAC by Director

AARB Annual meeting election of Chair and Secretary

As of May 2002:

George Mills, Term end 2002
Judy Duncan, Chair, Term end 2003
Carol Madding Secretary, Term end 2004
Carl Kirchner, Term end 2005
Dan Hickman, Term end 2006

Document control system for the AARB Documents

1. Final document: Footers: AARB and title of document on left, Date Effective on right
2. Draft document: draft in title, revision date
3. Font: Times New Roman
4. The permanent files for the AARB shall be maintained with NELAP permanent files

B. Appeals

AARB Appeal Board Functions

1. When a review of an appealed NELAP decision is requested, this activity should take priority over any routine annual business except election of officers.
2. The groups who are interviewed during AARB review of an appeal should be asked for feedback on the process so that it can be continually improved.

Standard Operating Procedure for AARB Investigation of Appealed NELAP Decisions (revised January 13, 2001)

The Accrediting Authority Review Board is charged by charter and by NELAC standards with reviewing appeals of NELAP decisions. When the NELAP Director informs the AARB that an Accrediting Authority has appealed a decision, the AARB will have 90 days to make a recommendation to the NELAP Director. The following process will be followed by the AARB to investigate the appeal.

1. The Chair of the AARB will request that the NELAP Director provide copies of all pertinent correspondence to the members of the AARB. This material will be requested in electronic format, if possible.

2. The AARB will meet by conference call to review the written record and prepare separate lists of questions for both the NELAP Director and the appealing Accrediting Authority. These questions may include requests for additional written documentation.
3. When the lists of questions are finalized, the AARB Chair will transmit the lists to both the NELAP Director and the appealing Accrediting Authority by e-mail along with proposed dates for conference calls with the AARB.
4. The AARB will meet by conference call with the NELAP Director and the appealing Accrediting Authority. These conference calls will be held separately to afford each party the opportunity to discuss their position openly with the AARB. Both the NELAP Director and the appealing Accrediting Authority may involve whatever staff members they believe may be necessary to fully represent their position to the AARB. During these calls additional documentation may be requested.
5. The AARB will meet by conference call to review the results of the initial investigation and decide upon next steps that may include:
 - Further review of additional documentation and/or additional conference calls that may be separate with each party or three-way with the AARB and both parties
 - Interviews with Assessment Team members who were involved in inspections of the appealing Accrediting Authority
 - Visits to the appealing Accrediting Authority or the NELAP Director for more in-depth review of the issues under appeal
 - Suggestions to both parties for an informal resolution to the appeal, or
 - A written recommendation to the NELAP Director for resolution of the appeal.

C. Monitoring NELAP

Review of a portion of On-site Assessment Reports of Accrediting Authorities

In order to ascertain if Accrediting Authorities were reviewed in a consistent manner, the AARB will review some or all of the reports generated by the review team. The following process will be used. The AARB shall request a list of AAs that were recognized in the previous year (since the last review). The list should include the names of the AAs requesting accreditation, the fields of testing for which they wish to be recognized and the names of the team members who reviewed the AAs application and performed the on-site visit.

1. The Chair of the AARB shall request that the NELAP Director send copies of some or all of the final summary reports of the reviews to the Board.
2. Using the checklist, each member of the Board shall read the reports and note any inconsistencies among them.
3. The Board may request copies of the complete audit reports if it is deemed necessary.
4. If clarification or more information about an assessment is necessary, the AARB may choose to interview AA personnel or assessor team members. The interview could be done by conference call or in person. The AARB will decide whom they want to interview and one member of the team will contact the person(s) to arrange for a convenient time for all to talk.

Review of NELAP SOPs and Documents

To ensure that activities are in conformance with NELAC policies and that these policies are applied consistently and will continue to be applied consistently, the AARB has requested that NELAP develop SOPs to describe its administrative tasks. As they are developed the AARB will review these documents both for content and comprehensiveness.

Review of NELAP Internal Audit

In the event that NELAP does internal audits of its program the AARB may review the procedures and practices which are used to conduct the internal audit. The in-house systems audit (by NELAP) would consist of reviewing the various aspects of the assessment and recognition activities. Checklists, which delineate the critical aspects of each area may be used during an internal audit and can serve to document all observations. AARB would review the QA plan and procedures used by NELAP when conducting an internal audit. At a minimum, the AARB suggests that the following topics be evaluated during the internal audit cycle:

Review Dates

- Documentation of dates of internal reviews

Quality System Plan:

- Approved/reviewed/present
- Procedures for document control
- Documentation of Procedures

Quality Control review:

- Turn around times
- Review of team reports
- Review of questions from teams
- Tracking of annual reviews and semiannual audits
- Assessment report Receipt and Storage
- Review Preparation
- Final recognition/denial/revocation letters/communications

Audits:

- External
- Tracking
- Checklists used
- Procedures used

Complaints:

- Review of complaints
- Review of appeals or other actions

Training:

- Assessor team training documentation review
- National program training reviews

Equipment and Resources:

- Personnel resources
- Budget resources
- Report to management.

Future:

- Future program needs and perceived impacts.

ATTACHMENT B

SUMMARY OF AARB RECOMMENDATIONS

Recommendations from 2000

NELAP Accrediting Process

1. NELAP should develop a Standard Operating Procedure (SOP) or SOPs to be used by Assessment Teams for document preparation and report format for Technical Assessments, Summary Reports and Final Recommendations regarding recognition of Accrediting Authorities.
2. NELAP should develop a record retention policy and procedure. Include how records can be retrieved and located from regions as well.
3. The AARB would like to review the NELAP formal record of decisions with the next review. The final record of decision should be included with the Summary Report Package.
4. NELAP should document the Conflict of Interest issues between the Assessment Team and the Accrediting Authority have been formally addressed.
5. Based on experience, NELAP should suggest timeline changes which will more closely reflect the actual time it will take to assess an Accrediting Authority under the NELAC standards.

Revocation Procedure

When an action to revoke an Accrediting Authority's (AA) recognition is being either considered or is imminent it is suggested as a matter of procedure that the NELAP Director send a notice of intent to the AA with a short time (ten working days) to respond and resolve any misunderstandings.

Recommendations from 2001

AARB Comments NELAP'S 2001 Documents

The NELAP Director asked the AARB to review several communications and documents as described below.

1. The AARB reviewed correspondence, which indicates that as a matter of procedure the NELAP Director is notifying AAs of possible revocation issues and asking for clarification and resolution prior to any revocation action.
2. The AARB reviewed the Cover letter for two year renewal of NELAP Accrediting Authorities, Standard Operating Procedure, Two Year Renewal of NELAP Accrediting Authorities (February 12, 2001), Application for two year renewal and Checklist to Determine Accrediting Authority Compliance revision 2, February 2001. The AARB was pleased to review these documents especially the first of SOPs. We found that the documents were more than adequate to get the renewal cycle started.

Comments: AARB advises that the 2000 recommendations it made be incorporated into the Standard Operating Procedure, Two Year Renewal of NELAP Accrediting Authorities (February 12, 2001), before the renewal cycle is substantially completed.

- a) Specify a list of documents/files to be created and where and in what form (i.e. hard copy or electronic file) they are to be kept (the Record).
 - b) Specify what the Record should contain: NELAP renewal application checklist completed by AA; Documentation that checklist has been reviewed and cross-checked by the AA assessment team (i.e. how/where is the requirement met); Copies of AA internal audits; either copies or listings of the accredited laboratory records reviewed; copies of all correspondence related to Corrective Action, Responses/ Reports and a copy of the final record of determination to grant or deny recognition.
 - c) Outline what should be in a final report to the Director and what the sections should contain (create report format).
 - d) Suggest adding a column on the checklist for the NELAP Assessment team to document its review.
 - e) Section C, 2, (7). AARB suggests that the wording be changed .../- Select a representative sample of files to review to reflect the work of all assessors. We recommend this change to insure that both small AAs and large AAs are reviewed in an equitable fashion.
 - f) The record should also include requested changes to the fields of testing an AA is recognized.
 - g) AARB is concerned that the timeline may not be adequate for renewal reviews to occur.
- For the NELAP Director: Specify either in this SOP or another where the record of final determination is kept and what will it contain.

ATTACHMENT C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY National Environmental Laboratory Accreditation Program (NELAP) ACCREDITING AUTHORITY REVIEW BOARD CHARTER

1. PURPOSE AND AUTHORITY. This Charter describes the roles and responsibilities of the NELAP Accreditation Authority Review Board (AARB). The Charter shall be reviewed each year at the NELAC Annual Meeting and revised as necessary by EPA.
2. OBJECTIVES. The AARB is established to provide advice to the NELAP Director, to perform an independent review of the EPA/NELAP's Accrediting Authority recognition process for consistent and appropriate application of the NELAC standards, and to serve as a review board where NELAP recognition is denied or revoked.
3. DUTIES AND SCOPE OF ACTIVITIES. The AARB is an advisory board that reports to the NELAP Director. In all cases, the Director makes the final decision. The AARB has responsibilities to:
 - ❖ monitor NELAP to assure that EPA is following the NELAC standards for recognizing accrediting authorities;
 - ❖ serve as a review board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked, providing advice to the NELAP Director;
 - ❖ report on its activities to the NELAC Board of Directors at each annual meeting;
 - ❖ conduct an annual ~~audit~~ review of the NELAP process for recognizing accrediting authorities in accordance with the appropriate NELAC standards,
 - reporting its findings at the general opening session of each NELAC annual meeting, and
 - providing the annual ~~audit~~ review for posting on the NELAC web site; and
 - ❖ provide advice on issues referred by the NELAP Director, which may include matters raised by entities other than the accrediting authorities.
4. COMPOSITION. The AARB is composed of five voting members and one non-voting member. Each member shall be appointed for a five-year term.
 - ❖ The non-voting member shall be a representative of the USEPA and appointed by the NELAP Director. The appointment should be rotated among the EPA Regions and EPA Headquarters.
 - ❖ The five voting members shall consist of one federal accrediting authority official and four members from either states, the Territories, the Possessions of the United States or the District of Columbia, accrediting authority officials, of which at least three must be from NELAP-recognized primary accrediting authorities.
 - The state accrediting authority officials should be from different EPA Regions.
 - The appointments must be made in such a manner that the correct mix of membership is maintained at all times. Any AARB member appointed prior to July 1, 1999 will remain an AARB member even though the correct mix of membership may not be attained until July 1, 2004.
 - ❖ Appointments to the AARB are made by the NELAP Director after consultation with the NELAC Board of Directors. The Director will solicit nominees from the NELAC stakeholders and present them to Board of Directors. Nominations are to be submitted to the NELAP Director three months prior to the NELAC annual meeting.
 - ❖ Voting members of the AARB shall not be NELAP staff, on the NELAC Board of Directors or a member of a NELAC standing committee. The AARB annually selects one of its members to serve as its chair. The AARB may establish subcommittees as it finds necessary to carry out its responsibilities. Such subcommittees will report back to the AARB.
5. MEETINGS. AARB will meet at least two times in person during the year at the NELAC annual meeting and at the interim meeting. Other meetings shall be held as needed.

ATTACHMENT D

QUALITY SYSTEM AND QUALITY MANUAL
FOR
ACCREDITING AUTHORITY REVIEW BOARD'S
ANNUAL ASSESSMENT OF THE
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

Revision 0
Draft May 29, 2002

1:1 of 2

5/29/02

Section 1: 2 Total Pages

TABLE OF CONTENTS

Section 1

Title Page	1:1 of 2
Table of Contents	1:2 of 2

Section 2: 6 Total Pages

Section 2	AARB as an assessment body	
2.1.1.1		2:1 of 6
2.1.1.2		2:1 of 6
2.1.1.3		2:1 of 8
2.1.1.4		2:1 of 8
2.1.2		2:2 of 8
2.1.3		2:3 of 8
2.1.4		2:3 of 8
2.1.5		2:5 of 8
2.1.6		2:5 of 8
2.1.7		2:5 of 8
2.1.8		2:5 of 8
2.1.9		2:5 of 8
2.2.1.1		2:6 of 8
2.2.1.2		2:6 of 8
2.2.1.3		2:7 of 8
2.2.2		2:7 of 8
2.2.3		2:7 of 8
2.2.4		2:8 of 8
2.2.5		2:8 of 8
2.2.6		2:8 of 8
2.3		2:8 of 8
2.4		2:8 of 8
2.5		2:8 of 8
2.6		2:8 of 8
2.7		2:8 of 8

	Section 3 3 Total Pages	
Section 3	Technical Requirements for Evaluations	
3.1.1.1		3:1 of 4
3.1.1.2		3:1 of 4
3.1.2		3:1 of 4
3.2.1		3:1 of 4
3.2.2		3:2 of 4
3.2.3		3:2 of 4
3.2.4		3:2 of 4
3.2.5		3:2 of 4
3.3		3:2 of 4
3.4.1		3:2 of 4
3.4.2		3:3 of 4
3.5		3:3 of 4

Accrediting Authority Review Board Charter

2 Total Pages

Section 4

NELAP Annual Audit Checklist

29 Total Pages

1:2 of 2

5/29/02

SECTION 2

AARB as an assessment body

2.1.1.1 Policy

This quality system, as described in this quality manual, delineates the functions and operations of the Accrediting Authority Review Board (AARB) in performing its annual assessment the United States' National Environmental Laboratory Accreditation Program (NELAP). The policies and procedures through which this is accomplished is outlined in this quality manual.

Chapter 6 of the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC Standards) was selected as the principal source of assessment criteria because this document is explicitly mentioned in the AARB Charter for this purpose. ISO Guide 61 has been selected as a secondary source of assessment criteria because the objectives of this Guide closely match the desired objectives of NELAP in recognizing accrediting authorities (AA's) and in accrediting qualified environmental testing laboratories. To paraphrase, the desired result of NELAP is to promote equivalence of AA's in granting laboratory accreditations, to facilitate agreements on mutual recognition of accreditations between the NELAP-recognized AA's, and to provide assurances that the public and commercial interests of accredited laboratories and their clients can rely on certificates issued by the AA's.

2.1.1.2

The AARB has been chartered through the United States Environmental Protection Agency (US EPA) to provide advice to the Director of NELAP, to perform an independent review of the EPA/NELAP Accrediting Authority recognition process for consistent and appropriate application of the NELAC Standards, and to serve as a review board where NELAP recognitions are denied or revoked. Since the AARB exists only this EPA Charter, the annual assessment services provided are accessible only to NELAP. Nevertheless, through each member's agreement to follow this quality system, the Board intends to assess NELAP professionally, consistently, and comprehensively in the style and manner that would be representative of an assessment of any other organization that could reasonably be assessed according to this quality system.

2.1.1.3

The AARB has adopted the international standards of ISO (International Organization of Standardization), Guide 62, "General Requirements for Bodies Operating Assessment and Certification / Registration of Quality Systems," 1996 version, to perform this assessment of NELAP. By consensus, the Board has agreed to assess NELAP according to Chapter 6 of the NELAC Standards. Where these standards are not clear or provide insufficient detail, this manual contains the international standards of ISO Guide 61, "General Requirements for Assessment and Accreditation of Certification/Registration Bodies," 1996

version, and supplemental standards from the International Laboratory Accreditation Cooperation (ILAC).

2:1 of 8

5/29/02

2.1.1.4

The requirements, assessments, and reports made regarding the Board's annual assessment of NELAP are confined to the delegated assignment contained in the AARB Charter and referenced in Section 1.6.3(e) of the NELAC Standards.

2.1.2 Organization

The Accrediting Authority Review Board consists of 5 voting members and one observer from the United States Environmental Protection Agency (EPA). The members are appointed by the NELAP Director after consultation with the NELAC Board of Directors. At least 3 voting members are from accrediting authorities (AA's) recognized by NELAP as compliant with the NELAC Standards for granting, amending, denying, limiting, or revoking environmental testing laboratory accreditations. These three members each come from different EPA regional jurisdictions. All other members are appointed from other laboratory accrediting authorities or from federal and state regulatory agencies that are responsible for administering environmental monitoring programs. Board members are appointed to 5-year terms, with one member rotating off and replaced at the end of each annual NELAC conference and voting session.

The NELAP Director is a full-time EPA employee. The Director appoints the members of the AARB, yet the NELAC Standards charge the Board with performing an annual audit of the NELAP process for recognizing AA's. The NELAP Director also is responsible for appointing the evaluation teams that determine the recognition status of AA's. At least one member of the evaluation team is appointed from the EPA Region where the applicant AA is located, and at least one other member is appointed from another, state laboratory AA.

Despite the inherent potential for conflict-of-interest within this framework, the AARB attempts to organize and perform its annual assessment of NELAP according to highest standards of professionalism and integrity possible. The goals of the AARB in conducting this annual assessment are as follows:

- (a) Be impartial;
- (b) Be responsible for the content of the report of the annual NELAP assessment that is delivered to the annual voting session of NELAC;
- (c) Assume overall responsibility for:
 - performing the annual assessment of NELAP,
 - formulation of policy matters relating to this assessment,
 - reporting assessment findings and making recommendations on NELAP's operations and processes,
 - supervision of the implementation of its policies,
 - delegation of authority to committees to undertake defined activities on its behalf, as required, although it's the primary intention of the Board not to delegate any such authority;
- (d) Have documents that demonstrate that it is operating as charged according to its Charter;
- (e) Have documented structure that safeguards confidentiality and enables participation of all parties concerned in development of policies and principles regarding content and functioning of the annual assessment of NELAP;

(f)-(i) not relevant to the AARB in this function;

2:2 of 8

5/29/02

(j) Through the NELAP Director's appointment criteria based on knowledge and experience, use all AARB members since they have training, education, technical knowledge, and experience for performing accreditation functions under a responsible Board member who is elected as its Chair;

(k) Have a quality system giving confidence in its ability to conduct the annual audit of NELAP;

(l) Have policies and procedures to distinguish between assessments and any other activities in which it is engaged;

(m) Be free from commercial, financial, or other pressures that might influence the results of the NELAP assessment;

(n) Have formal rules and structures for the appointment of any committees involved with the assessment process;

(o) Ensure that activities of NELAP do not offer or provide:

- services that it accredits laboratories to perform,
- consulting services to obtain or maintain accreditation,
- service to design or implement a certification scheme; and

(p) Have policies and procedures for resolution of complaints, appeals, and disputes about the handling of annual NELAP assessment or any related matters.

2.1.3

At present AARB does not intend to subcontract any portion of its annual assessment of NELAP to another committee, organization, or agency.

2.1.4 Quality System

The quality policy statement for the AARB is contained within Sections 2.1.1.1 through 2.1.1.4 of this quality manual. This manual and any quality documentation that are incorporated by reference are intended to be fully documented public information, accessible to the Board members when the annual NELAP assessment is conducted, and freely available for anyone to review. Collectively, all Board members are responsible for ensuring its effective implementation, up-to-date maintenance, and overall performance.

The quality elements contained within this manual are as follows:

(a) Quality policy statement is contained within Sections 2.1.1.1 through 2.1.1.4 above.

(b) The AARB has whatever legal status exists for an EPA advisory committee, with the duties and responsibilities contained therein.

(c) As of the effective date of this quality manual, the AARB members are as follows:

Judy Duncan, Chair, Oklahoma Department of Environmental Quality
George Mills, Vermont Department of Health
Dan Hickman, Oregon Department of Environmental Quality
Caroline Madding, US EPA Office of Groundwater & Drinking Water
Carl Kircher, Florida Department of Health

Each member has extensive experience in performing laboratory accreditation assessments, operating environmental testing laboratory accreditation programs, and/or implementing regulatory environmental monitoring programs.

2:3 of 8

5/29/02

(d) The organization and lines of responsibility of the AARB are delineated in Section 2.1.2. The assignments and business agenda of this Board are made from the NELAC Standards and from the NELAP Director. The AARB reports to the NELAP Director. The Board makes no decisions made regarding the efficacy or viability of NELAP based on the assessment conducted; the only product is the report of the assessment findings of NELAP made to the participants at the NELAC Conference and voting session.

(e) The AARB organization, membership, and functions are described in its Charter and referenced in Section 1.6.3 of the NELAC Standards and in Section 2.1.2 of this quality manual. Rules of procedure, particularly for meetings and conference calls, are generally in conformance with Roberts Rules of Order.

(f) There are currently no procedures in place for management review of this quality system. It is anticipated that findings from the annual assessment of NELAP, feedback from relevant NELAP personnel regarding the assessment and reporting procedures, recommendations made to NELAP as part of the annual assessment, and feedback from the NELAC Conference as to the sufficiency and completeness of the annual NELAP assessment will be used to revise this quality system and associated quality documentation as necessary.

(g) Document control of this quality manual, associated quality documentation, and reports will be handled through the regular meeting and teleconference calls of the AARB.

(h) Each member of the AARB takes equal responsibility for ensuring that the most recently approved documents are used in the annual NELAP assessment and that the scope of the assessment is confined to the objectives in this quality manual, the AARB Charter, and the applicable NELAC Standards.

(i) Each member of the AARB is appointed by the NELAP Director as described in Section 2.1.2. There is no current provision for monitoring on-going performance; however, remedial action can be taken if substandard performance has been made. The most anticipated substandard performance is non-participation in meetings and teleconferences, and the NELAC policies on committee participation would be extended to the AARB matters in this instance.

(j) The AARB does not intend to use any subcontractors for carrying out its assignment of performing the annual audit of NELAP.

(k) Nonconformances will be handled by additional training and mutual dialogue among the AARB members to ensure that either the documented quality manual procedures will be followed or that the quality manual will be revised to incorporate more effective procedures for the NELAP assessment. Effectiveness will be gauged through assessment findings that show NELAP (AA evaluators and AA's) in consistency and conformance with implementing the NELAC Standards, and through general comments at the NELAC voting session from participants that indicate acceptance of the reported NELAP assessment findings and confidence that the objectives for the NELAP annual assessment are being addressed.

(l) AARB will make no accreditation decisions or impose any conditions on NELAP as a result of the annual assessment. No certificates or documents of accreditation will be issued to NELAP as a result of the assessment. Nevertheless, the procedures to be used in the annual assessment are contained in this quality manual, and the AARB highly recommends that NELAP incorporate any relevant procedures to address or correct assessment findings so that the goal described in Section 2.1.1.1 of this quality manual and in the AARB Charter can be achieved.

(m) There are no AARB accreditation decisions with which NELAP will need to appeal. However, AARB intends to address any complaints or disputes received through meeting and teleconferences among its members and to report any findings and recommendations to the NELAP Director, who in turn will act on these findings and recommendations and communicate these to the NELAC Board of Directors and to the NELAC Conference.

(n) No internal audits or management reviews of this quality system are planned. However, any nonconformances identified during the annual assessment of NELAP will be addressed as indicated in Section 2.1.4(k) above.

2.1.5 <see Section 2.1.4(l)>.

2.1.6 <see Section 2.1.4(n)>.

2.1.7 Documentation

The available AARB documentation for the annual audit of NELAP includes the following:

- Chapter 6 of the NELAC Standards, which show the criteria under which the annual assessment of NELAP is being conducted.

- Information about the assessment process, as contained in this quality manual.

- Information for handling complaints and disputes as described in the AARB SOP, "SOP for AARB Investigation of Appealed NELAP Decisions" (January 2000).

2.1.8 Records

Records will be formulated, copied, distributed, and maintained by each individual AARB member. Each member will have his/her relevant copy, and no centralized recordkeeping source for documents will be maintained. The records should be maintained by NELAP for 5 years after the date that the annual audit is performed. AARB records will be kept with the other NELAP records in Las Vegas, NV. The AARB chair is responsible for sending the records to Las Vegas.

2.1.9 Confidentiality

The AARB does not intent to safeguard any documents used in the annual assessment process. The documents and records are in the public domain and subject to regulations governing public records.

2:5 of 8

5/29/02

2.2.1.1

The NELAP Director appoints the members of the AARB according to each person's particular merits, experience, and knowledge. The NELAP Director also attempts to balance the membership to the degree possible taking the following into consideration:

- no concurrent members from the same state, federal agency, or EPA Office or Region;
- type of state or federal program (i.e., laboratory accreditation, drinking water only, comprehensive program covering air, water, waste, etc.);
- size of state;
- geographic distribution.

2.2.1.2

For the current membership of the AARB, our qualifications, training, and experience are as follows:

Judy Duncan, Oklahoma Dept. of Environmental Quality

George Mills, Vermont Department of Health

Dan Hickman. Oregon Department of Environmental Quality

Caroline Madding, EPA Office of Water
Office of Groundwater and Drinking Water
Responsible for oversight of the Drinking Water Laboratory Certification Program

Carl Kircher, Florida Dept. of Heath

Ph.D. Analytical Chemistry and Bachelor of Science degree in Chemistry
9 years with the department assessing laboratories and administering the certification process
8 years with Unocal Corporation developing analytical test methods and coordinating projects that included independent audits of air, water, solids, industrial hygiene, and medical surveillance monitoring
EPA Laboratory Certification Officer training courses in Chemistry and Microbiology
NELAC Accrediting Authority Evaluator training course
NELAC Basic Laboratory Assessor training

2.2.1.3

The duties and responsibilities of the AARB are given in its Charter and referenced in Section 1.6.3(e) of the NELAC Standards. They are summarized here as follows:

- monitor NELAP to assure that EPA is following the NELAC Standards for recognizing accrediting authorities;
- serve as a review board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked, and providing advice to the NELAP Director who will make the final decision;
- report on its activities annually to the NELAC Board of Directors;
- conduct an annual assessment of the NELAP process for recognizing accrediting authorities in accordance with the appropriate NELAC Standards (the findings from this assessment are to be reported at the general opening session of each NELAC annual meeting, and the report from this assessment is to be posted on the NELAC computer internet site);
- provide advice on issues referred by the NELAP Director, which may include matters raised by entities other than accrediting authorities.

2.2.2

The qualification criteria for the AARB members for assessing NELAP are the same as used by the NELAP Director to appoint the Board members in the first place. No attempt was made to refer to relevant international documentation on evaluator qualifications, although it is hoped that each members' qualifications as given in Section 2.2.1.2 above provide substantial compliance.

2.2.3

The selection process for the assessors of the NELAP process is the same as for appointment of members to the AARB. All members of the AARB are expected to participate in the assessment process. There is no current provision for monitoring on-going performance of AARB members as assessors other than feedback from NELAP personnel and NELAC conferees as mentioned for the internal audit provisions of Sections 2.1.4(k) and (n) of this quality manual.

The AARB members can claim the ability to communicate effectively orally and in writing. Within the constraints listed in Section 2.1.2 of this quality manual, the Board members can claim freedom from conflict-of-interest enough to perform assessment functions in an impartial nondiscriminatory manner. As participants in NELAC, the AARB members are fully competent with the procedures and requirements to assess NELAP's process for recognizing accrediting authorities according to the NELAC Standards but may lack extensive working knowledge of ISO Guides 61 and 62 for this purpose. Nevertheless, the Board intends not to be deterred by these limitations and intends to assess NELAP according to the objectives already described in its Charter and in Section 2.1.1.2 of this quality manual.

2.2.4

By signing and ratifying this quality manual, each AARB member has agreed to comply with the requirements contained herein, including matters relating to confidentiality, links to any aspects of NELAP to be assessed, and independence from commercial or other interests.

2.2.5 <see Section 2.2.1.2>

2.2.6

The instructions and relevant information for assessing NELAP are contained within this quality manual and are accessible to all AARB members.

2.3

There are no decisions made about NELAP as an accreditation system made as a result of this annual assessment. No certificates or other credentials will be issued. No subcontractors will be employed to make such decisions either. Nevertheless, the findings from the annual assessment of NELAP, as reported to NELAC, are confined to information gathered solely from this assessment process as described in this quality manual.

2.4

There will be no logos or other references attesting to the efficacy of NELAP as an accreditation system made as a result of this annual assessment.

2.5

Any changes to the process of assessing NELAP will be made by revisions to this quality manual. These subsequent revisions will be provided to the NELAP Director, the NELAC Board of Directors, and to interested participants at the NELAC voting session.

2.6

The procedures and records kept on any complaints or disputes (there are no decisions to appeal) are given in Section 2.1.4(m) of this quality manual.

2.7

Records of any AARB handling of complaints or disputes will be reported at the annual NELAC meeting, the minutes of which will be posted on the NELAC computer internet site.

Section 3 Technical Requirements for Evaluations

3.1.1.1

The detailed description of the evaluation and recognition procedures for the annual assessment of NELAP is contained within this quality manual. This document will be provided to the NELAP Director, in preparation for the annual assessment, upon its ratification.

3.1.1.2

In conducting the annual assessment, the AARB can only require that NELAP make arrangements for the evaluations, including examining NELAP documentation, access to all areas, records (e.g., AA evaluation reports), and personnel for purposes of assessment, surveillance, and resolution of complaints. All other requirements in ISO Guide 61 Sections 3.1.1.2 through 3.1.1.4 are not applicable to this annual assessment.

3.1.2

There is no application form that NELAP must complete in order for the annual assessment to take place. However, AARB should require that NELAP provide information necessary to determine conformance with relevant national, international, and NELAC Standards for recognizing accrediting authorities. This documentation can include the following:

- NELAP's organization or affiliation, addresses, legal status, and relevant human and technical resources;
- NELAP's functions, physical locations, and relationships within the larger organization;
- description of the accrediting authority recognitions it offers, plus the standards or regulations applicable to each; and
- copy of NELAP's quality manual and any required associated documentation.

3.2.1

To the extent possible, the AARB reviews, and maintains records of such reviews, the above NELAP information to ensure that NELAP annual assessment objectives are clearly defined, any differences between NELAP and the AARB are resolved and AARB has the ability to perform the assessment process with respect to NELAP's accreditation system, physical location, and any special requirements (e.g., languages used).

3:1 of 4

5/29/02

3.2.2

The AARB's plan for its annual assessment activities consists of reviewing accrediting authority recognition and evaluation documents that can be provided to Board members on-line, performing on-site inspections of NELAP facilities where such records are stored, and interviewing NELAP personnel and accrediting authority evaluators as necessary to determine that recognitions

are made in conformance with relevant national, international, and NELAC Standards.

3.2.3

The entire AARB serves as the NELAP assessment team.

3.2.4

Since the Board members are appointed by the NELAP Director, there should be no confusion from NELAP regarding the composition of the assessment team nor any cause for appealing the appointment of any particular AARB members on the team.

3.2.5

The AARB's plan for and date of the annual assessment will be made with the mutual agreement of the NELAP Director.. Since the AARB's mandate to assess NELAP is clearly defined in the NELAC Standards, this mandate should already be known to all NELAP personnel. The AARB will assess NELAP's structure, policy & procedures, to confirm compliance with NELAC requirements with respect to recognizing accrediting authorities, and to confirm NELAP's implementation of procedures so as to give confidence in the NELAP recognitions bestowed to accrediting authorities.

3.3 Assessment of NELAP

The AARB will assess all NELAP services covered by the defined scope of recognition statuses (e.g., NELAP Fields of Accreditation) against the relevant national, international, and NELAC Standards pertinent to accrediting authority recognition. The AARB may, as part of this assessment, witness the assessment activities of NELAP evaluation teams on 1-2 accrediting authorities during the recognition process.

3.4.1 Assessment Report

The AARB's reporting procedures on the annual assessment of NELAP will ensure that:

(a) a meeting occurs between the AARB assessors and the NELAP's personnel prior to leaving the premises of any remote-site inspection, at which the AARB members will provide indication of the NELAP's conformity to the relevant national, international, and NELAC Standards for recognizing accrediting authorities, and at which the NELAP personnel can ask questions about the findings and their bases;

3:2 of 4

5/29/02

(b) at the annual NELAC meeting, the AARB will give the NELAP Director, the NELAC Board of Directors, and the NELAC conference a report of the findings as to the NELAP's conformity with relevant national, international, and NELAC Standards for recognizing accrediting authorities;

(c) this report is addressed to the NELAP Director and identifies any nonconformities to be corrected in order to comply with relevant national, international, and NELAC Standards for recognizing accrediting authorities;

(d) AARB invites all NELAP personnel to comment on the report and to describe the actions taken or planned to remedy any nonconformities with relevant national, international, or NELAC Standards for recognizing accrediting authorities as identified during the annual assessment, and the AARB informs the NELAP Director as to whether a full or partial re-assessment or written declaration to be confirmed during future annual assessments is needed; and

(e) the report contains the dates of any on-site inspections made, names of the AARB personnel responsible for the report, names and addresses of all NELAP sites evaluated, comments on NELAP's conformity with relevant national, international, and NELAC Standards for recognizing accrediting authorities (and any comparisons with the results of previous annual assessments of NELAP where applicable), and explanations of any differences in the information presented to NELAP personnel at closing meetings.

3.4.2

If the final report from the AARB to the NELAP Director differs from the information presented at closing meetings, the AARB's final report will explain any such differences take into consideration:

- (a) qualifications, experience, and authority of the staff encountered;
- (b) adequacy of the NELAP's internal organization and procedures to give confidence in the quality of its recognitions bestowed to accrediting authorities; and
- (c) actions that NELAP has taken to correct identified nonconformities (including those nonconformities identified during previous annual assessments).

3.5 Procedures for Subsequent NELAP Annual Assessments

The NELAC Standards provide for the AARB to conduct the assessment of NELAP on an annual basis to verify that NELAP continues to comply with relevant national, international, and NELAC Standards for recognizing accrediting authorities. AARB procedures for subsequent assessments of NELAP are consistent with the initial first-time assessment unless this quality manual or the relevant national, international, and NELAC Standards for recognizing accrediting authorities are revised.

3:3 of 4

5/29/02

The AARB has arrangements to ensure that NELAP informs the AARB without delay of any changes in its operations that affect its legal or organizational status, organization and management, policies and procedures where appropriate, premises, and personnel, equipment, facilities, working environment, or other resources where significant. NELAP must also inform the AARB of any other matters that may affect its capability, scope of recognized activities, or conformance with national, international, or NELAC Standards for recognizing accrediting authorities.

3:4 of 4

5/29/02

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Environmental Laboratory Accreditation Program (NELAP)
ACCREDITING AUTHORITY REVIEW BOARD CHARTER

1. PURPOSE AND AUTHORITY. This Charter describes the roles and responsibilities of the NELAP Accreditation Authority Review Board (AARB). The Charter shall be reviewed each year at the NELAC Annual Meeting and revised as necessary by EPA.

2. OBJECTIVES. The AARB is established to provide advice to the NELAP Director, to perform an independent review of the EPA/NELAP's Accrediting Authority recognition process for consistent and appropriate application of the NELAC standards, and to serve as a review board where NELAP recognition is denied or revoked.

3. DUTIES AND SCOPE OF ACTIVITIES. The AARB is an advisory board that reports to the NELAP Director. In all cases, the Director makes the final decision. The AARB has responsibilities to:

- monitor NELAP to assure that EPA is following the NELAC standards for recognizing accrediting authorities;
- serve as a review board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked, providing advice to the NELAP Director;
- report on its activities to the NELAC Board of Directors at each annual meeting;
- conduct an annual audit of the NELAP process for recognizing accrediting authorities in accordance with the appropriate NELAC standards,
 - reporting its findings at the general opening session of each NELAC annual meeting, and
 - providing the annual audit for posting on the NELAC web site; and
- provide advice on issues referred by the NELAP Director, which may include matters raised by entities other than the accrediting authorities.

4. COMPOSITION. The AARB is composed of five voting members and one non-voting member. Each member shall be appointed for a five-year term.

- The non-voting member shall be a representative of the USEPA and appointed by the NELAP Director. The appointment should be rotated among the EPA Regions and EPA Headquarters.
- The five voting members shall consist of one federal accrediting authority official and four state accrediting authority officials, of which at least three must be from NELAP-recognized state accrediting authorities.
 - The state accrediting authority officials should be from different EPA Regions.
 - The appointments must be made in such a manner that the correct mix of membership is maintained at all times. Any AARB member appointed prior to July 1, 1999 will remain an AARB member even though the correct mix of membership may not be attained until July 1, 2004.

- Appointments to the AARB are made by the NELAP Director after consultation with the NELAC Board of Directors. The Director will solicit nominees from the NELAC stakeholders and present them to Board of Directors. Nominations are to be submitted to the NELAP Director three months prior to the NELAC annual meeting.
 - Voting members of the AARB shall not be NELAP staff, on the NELAC Board of Directors or a member of a NELAC standing committee. The AARB annually selects one of its members to serve as its chair. The AARB may establish subcommittees as it finds necessary to carry out its responsibilities. Such subcommittees will report back to the AARB.
5. MEETINGS. AARB will meet at least two times in person during the year at the NELAC annual meeting and at the interim meeting. Other meetings shall be held as needed.

SECTION 4
CHECKLIST FOR ANNUAL NELAP ASSESSMENT
Based on Chapter 6 of the NELAC Standards

SITE INSPECTED: _____

Physical Address: _____

Mailing Address: _____
(if different from above)

Telephone Number: _____ Facsimile Number: _____

E-mail address: _____

EVALUATED BY: (Name) (Affiliation)

EVALUATION DATES: _____

PARTICIPATING NELAP PERSONNEL AND MANAGEMENT: (Name) (Title)

GENERAL INSTRUCTIONS: Before each item is a blank line and an ISO Guide 61 or NELAC Standard citation in Bold Numerals.

Place a check mark (or "YES") in the blank if NELAP meets the Standard referenced.

Place an X-mark (or "NO") in the blank if the Standard is not met and Whether NELAP should devise an acceptable Plan of Correction and estimated completion date.

Mark "N/A" in the blank if the national, international, or NELAC Standard is not applicable or was not assessed, either because of the nature of its business mission, because of the scope of Fields of Accreditation with which it wants to oversee, or because of the situation never ever happening.

Notes:

NELAP stands for the National Environmental Laboratory Accreditation Program
NELAC stands for the National Environmental Laboratory Accreditation Conference
AARB stands for the Accrediting Authority Review Board

COMMENTS ON THE COMPONENTS OF NELAP ASSESSED:

APPLICATION COMPLETENESS REVIEW BY NELAP

NELAC 6.3.1(d)(1) - Has NELAP sent, by certified mail or some other verifiable means, to the recognized accrediting authority, no later than 180 calendar days prior to the expiration of the accrediting authority's then-current NELAP recognition, an application for renewal of NELAP recognition to the accrediting authority?

NELAC 6.3.1(d)(1) – Does the NELAP renewal notification indicate whether an on-site assessment will be due?

NELAC 6.3.2(b) – Does NELAP notify the accrediting authority of NELAP's non-receipt of a recognition renewal application within 30 days of the initial notification?

NELAC 6.3.2(c) – Does NELAP conduct a completeness review of initial and renewal applications, and supporting documentation, from accrediting authorities to ensure that the following elements are present?

NELAC 6.3.1(b)(1) - Name, mailing address, telephone number, electronic mail address and telefacsimile number of the accrediting authority.

NELAC 6.3.1(b)(2) - Statutes and regulations establishing and governing the accrediting authority's environmental laboratory accreditation program.

NELAC 6.3.1(b)(3) - Policies, guidance documents, promulgating instructions and standard operating procedures governing the operation of the accrediting authority's environmental laboratory accreditation program.

NELAC 6.3.1(b)(4) - The accrediting authority's arrangements for liability insurance and workman's compensation insurance coverage.

NELAC 6.3.1(b)(5) - Requirements governing how the accrediting authority restricts the use of its accreditation by accredited laboratories.

NELAC 6.3.1(b)(6) - The fields of testing for which the accrediting authority is requesting NELAP recognition.

NELAC 6.3.1(b)(7) - Name and title of the primary person responsible for the day-to-day management of the accrediting authority's environmental laboratory accreditation program.

NELAC 6.3.1(b)(8) - Names, education, and experience levels of the accrediting authority's environmental laboratory accreditation program's management and technical staff.

NELAC 6.3.1(b)(9) - Names and contractual agreements for any external assessment bodies used by the accrediting authority.

NELAC 6.3.1(b)(10) - Names, areas of responsibility, education and experience levels of all technical and assessment employees of any external assessment bodies used by the accrediting authority.

NELAC 6.3.1(b)(11) – RESERVED

NELAC 6.3.1(b)(12) - Description of the accrediting authority's environmental laboratory accreditation program quality systems (e.g., a quality systems manual or a quality assurance plan).

NELAC 6.3.1(b)(13) - Procedures for the selecting, training, contracting and appointing of the accrediting authority's laboratory assessors.

NELAC 6.3.1(b)(14) - Description of the accrediting authority's conflict-of-interest disclosure program.

NELAC 6.3.1(b)(15) - Tabular listing of all laboratories applying for accreditation in the two-year period immediately preceding the date of the application. The table shall set forth the date on which the laboratory's application for accreditation was received by the accrediting authority and the date on which final action on the application was taken.

NELAC 6.3.1(b)(16) - Policies and procedures used by the accrediting authority for establishing and maintaining records on each accredited laboratory and procedures for record access and retention.

NELAC 6.3.1(b)(17) - The accrediting authority's findings, reports and corrective actions from internal audits conducted in the last two years.

NELAC 6.3.1(b)(18) - Certification that the accrediting authority meets the following provisions:

NELAC 6.2(a) - The accrediting authority is a governmental organization at the territory, state, or federal level.

NELAC 6.2(b) – The territory, state, or federal entity has designated the appropriate agencies or departments as its designated NELAP-recognized accrediting authority for the fields of accreditation for which NELAP recognition is being sought.

NELAC 6.2(c) – The accrediting authority does not delegate authority for granting, maintaining, suspending, or revoking a laboratory's NELAP accreditation to an outside person or body.

NELAC 6.2(d) - The procedures under which the accrediting authority operates are administered in an impartial and non-discriminatory manner. The accrediting authority also requires accredited laboratories to maintain impartiality and integrity. The accrediting authority has no rules, regulations, procedures or practices that:

- (1) restrict the size, large or small, of any laboratory seeking accreditation;
- (2) require membership or participation in any laboratory or other professional association;
- (3) impose any financial conditions or restrictions for participation in the accreditation program other than the fees authorized by territorial, Sstate or federal law; and,
- (4) conflict with any territorial, Sstate or federal laws governing discrimination.

NELAC 6.2(e) – The accrediting authority and its contractors shall confine their requirements, assessments and decision making processes for a NELAP accredited laboratory to those matters specifically related to the fields of accreditation of the NELAP accreditation being sought by a laboratory.

NELAC 6.2(f) - If NELAP-recognized, the accrediting authority shall accompany the display of any NELAP insignia with at least the phrase "NELAP-recognized."

NELAC 6.2(g) – The accrediting authority, within the scope and applicability of its prevailing rules and regulations, has established one or more technical committees for assistance in interpretation of requirements and for advising the accrediting authority on the technical matters relating to the operation of its environmental laboratory accreditation program. When such committees are established, the accrediting authority has:

- (1) formal rules and structures for the appointment and operation of committees involved in the accreditation process and such committees shall be free from any commercial, financial, and other pressures that might influence decisions, or
- (2) a structure where committee members are chosen to provide relevant competent technical support and impartiality through a balance of interests where no single interest predominates, and
- (3) a mechanism for publishing interpretations and recommendations made by these committees.

NELAC 6.2.1(a) & (b) - If NELAP-recognized, the accrediting authority grants reciprocal accreditation to laboratories, on a laboratory-by-laboratory basis within 30 days of the receipt date of its application, that accredited by any other NELAP-recognized primary accrediting authority for the fields of accreditation sought. The accrediting authority considers only the current certificate of accreditation issued by the NELAP-recognized primary accrediting authority.

NELAC 6.2.1(d) – The accrediting authority does not require the NELAP-accredited laboratory to meet any additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of accreditation for which the laboratory holds primary NELAP accreditation.

NELAC 6.2.2(h) – The accrediting authority processes applications for NELAP accreditation in the chronological order that the applications are received.

NELAC 6.2.3(a)(1) - The accrediting authority provides, through publication, electronic media, or other means, a document or documents describing its environmental laboratory accreditation program that include the following:

- (A) information setting forth the authority of the accrediting authority to grant laboratory accreditations and whether such laboratory accreditation is mandatory or voluntary;
- (B) information setting forth the accrediting authority's requirements for an environmental laboratory to become accredited;
- (C) information stating the requirements for granting, maintaining, withdrawing, suspending or revoking laboratory accreditation;
- (D) information about the laboratory accreditation process;
- (E) information on fees charged to applicants and accredited laboratories;
- (F) information regarding the rights and duties of accredited laboratories; and,
- (G) information listing its NELAP accredited laboratories describing the NELAP accreditation granted.

NELAC 6.2.3(a)(2), (b), & (c) – The accrediting authority reviews its environmental laboratory accreditation documents annually, updates any changes in documents based on this review within 30 days, and will make a written record of this review and any document changes available for inspection.

NELAC 6.2.3(d) - The accrediting authority has arrangements to safeguard information claimed by the laboratories as confidential.

NELAC 6.3.1(b)(19) - Name and job title of the individual or individuals authorized to sign accreditation certificates.

NELAC 6.3.1(b)(20) - The standardized checklist required by NELAC 6.3.2(c)(1) as completed by the applicant accrediting authority citing the location in the application or supporting documents where the checklist information is provided.

NELAC 6.3.2(c)(1) – Does NELAP use a standardized checklist, provided as part of the application, to conduct a completeness review of the application and supporting documents and to note the date the completeness review was completed?

NELAC 6.3.2(c)(2) – Does NELAP notify the accrediting authority in writing within 20 calendar days of receiving the application of any additional information needed to complete the application?

NELAC 6.3.2(c)(4) – Does NELAP notify the accrediting authority that an application is complete within seven calendar days of the date of such determination?

FORMATION OF NELAP ACCREDITING AUTHORITY EVALUATION TEAM

NELAC 6.9.1(a) – For each applicant accrediting authority, does the NELAP Director appoint NELAP evaluation team members and delegate the responsibilities required by NELAC Chapter 6 to this team?

NELAC 6.3.3(a)(4) – Does the NELAP Director appoint different NELAP evaluation team members for each succeeding four-year NELAP on-site assessment cycle of the accrediting authority, starting with each renewal application when an on-site assessment of the accrediting authority is required?

NELAC 6.9.1(c) – Does the NELAP evaluation team consist of at least one member who is an employee of the US EPA and at least one member who is an employee of a NELAP-recognized accrediting authority?

NELAC 6.9.1(d) – Has at least one member of the NELAP evaluation team completed the NELAP Accrediting Authority Evaluator Training Course?

NELAC 6.9.1(e)(1) – Does the NELAP evaluation team have at least one member who meets the education, experience, and training requirements for laboratory assessors specified in the NELAC Chapter 3, On-Site Assessment?

NELAC 6.9.1(e)(2) – Does the NELAP evaluation team have at least another member with experience that includes at least one of the following:

- (A) certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;
- (B) one year of experience implementing federal or State laboratory accreditation rulemaking;
- (C) laboratory accreditation management; or,
- (D) one year experience developing or participating in laboratory accreditation programs?

TECHNICAL REVIEW OF QUALITY SYSTEMS BY NELAP

NELAC 6.3.3(a) – Do the NELAP evaluation teams perform a technical review of the accrediting authority's application and supporting documents, and respond in writing to the accrediting authority, within 30 calendar days of the determination that the application is complete?

NELAC 6.3.3(a)(1) – Are the technical reviews of the accrediting authority's application and supporting documents conducted in accordance with the NELAP standard operating procedures for this review?

NELAC 6.3.3(a)(2) – Are the technical reviews of each accrediting authority performed by the same NELAP evaluation team assigned to conduct the on-site assessment?

NELAC 6.3.3(a)(3) - In the years when no on-site assessment is required, does the NELAP Director endeavor to appoint the same NELAP assessment team that conducted the application technical review and on-site assessment for the accrediting authority's immediately preceding application cycle?

NELAC 6.3.3(b) – Does the technical review evaluate whether the accrediting authority's environmental laboratory accreditation program requires its accredited laboratories to meet the NELAC Standards?

NELAC 6.3.3(c) - Does the NELAP evaluation team, if necessary, seek additional application information and documentation from the accrediting authority?

NELAC 6.3.3.1(a) – Does the technical review ensure that the accrediting authority's environmental laboratory accreditation program meets the following requirements?

NELAC 6.3.3.1(b) - The accrediting authority is legally identifiable governmental entity.

NELAC 6.3.3.1(c) - The accrediting authority has authority, rights, and responsibilities necessary to carry out an environmental laboratory accreditation program.

NELAC 6.3.3.1(d) - The accrediting authority has the same arrangements to cover liabilities and workman's compensation claims arising from its operations and activities as all other programs, units, divisions, bureaus, etc. in the department or agency in which the accrediting authority is located.

NELAC 6.3.3.1(e) - The accrediting authority has financial stability and the physical and human resources required for the operation of an accrediting authority's laboratory accreditation program. The accrediting authority shall have and make available on request a description of the means by which it receives its financial support.

NELAC 6.3.3.1(e) - The accrediting authority has the resources necessary to complete action on a laboratory's application within nine months from the time a completed application is first received from the laboratory. This time period applies as long as all turn-around times for responses to application review, proficiency testing, and on-site assessment issues are carried out within the required time limits set forth in the NELAC Standards.

NELAC 6.3.3.1(f) - The accrediting authority appoints and maintains records on assessors, including contractual assessors, who meet the education, experience and training requirements set forth in the NELAC Chapter 3.

NELAC 6.3.3.1(f) – The records on the accrediting authority's laboratory assessors include:

- (1) name and address;
- (2) organization affiliation and position held;
- (3) educational qualification and professional status;
- (4) work experience;
- (5) training applicable to laboratory accreditation;
- (6) experience in laboratory assessment, together with field of competence;
- and,
- (7) date of most recent updating of record.

NELAC 6.3.3.1(g) - The accrediting authority has a system in place to evaluate assessor performance that is consistent with the organizational employee evaluation program and demonstrates compliance with NELAC Chapter 3.

NELAC 6.3.3.1(h) - The accrediting authority identifies one individual responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program. This individual is an employee of the accrediting authority and has the technical expertise necessary to:

- (A) plan and manage the laboratory accreditation program,
- (B) coordinate various facets of the laboratory accreditation program with other territory, state, and federal accrediting authorities,
- (C) coordinate development of environmental laboratory accreditation regulations, and,
- (D) evaluate the technical competence and performance of contractors or employees.

NELAC 6.3.3.1(i) - The accrediting authority has arrangements to ensure that its management and technical staff are free of any commercial, financial, or other pressures that influence the results of the accreditation process and are subject to the same conflict of interest disclosure requirements designed to identify and eliminate potential conflict-of-interest problems as all other programs, units, divisions, bureaus etc. in the department or agency in which the accrediting authority is located.

NELAC 6.3.3.1(j) - The accrediting authority has a documented procedure in place to conduct systematic internal audits annually of its environmental laboratory accreditation program to verify compliance with the NELAC standards.

NELAC 6.3.3.1(j) – The accrediting authority's annual internal audit includes a review of the effectiveness of its quality system.

NELAC 6.3.3.1(k) - The accrediting authority designates an individual to take responsibility for the quality system and maintenance of the quality documentation.

NELAC 6.3.3.1(l) - The accrediting authority has established standard operating procedures for dealing with appeals, complaints, and disputes arising from denial, suspension, or revocation of laboratory accreditation, or from users of the services about the NELAP accredited laboratories or any other matters.

NELAC 6.3.3.1(m) - The accrediting authority requires NELAP-accredited laboratories to participate in a proficiency testing program meeting the requirements of the NELAC Chapter 2, Appendix A.

NELAC 6.3.3.1(n) - The accrediting authority or its contractors do not offer consultancy or other services which may compromise the objectivity or impartiality of its accreditation process and decisions.

NELAC 6.3.3.2(a) – Does the NELAP evaluation team accept an initial application and its supporting documentation for continued processing that contains sufficient information to determine that an accrediting authority meets the requirements of the NELAC Standards for designation as a NELAP-recognized accrediting authority?

NELAC 6.3.3.2(a) – Does the NELAP evaluation team schedule an on-site assessment of the accrediting authority when the team completes its review of an initial application and notes no deficiencies?

NELAC 6.3.3.2(b) – Does the NELAP evaluation team accept a renewal application and its supporting documentation for continued processing that contains sufficient information to determine that an accrediting authority meets the requirements of the NELAC Standards for designation as a NELAP-recognized accrediting authority?

NELAC 6.3.3.2(b) – Does the NELAP evaluation team recommend to the NELAP Director that NELAP recognition be maintained when the team completes its review of a renewal application and denotes no deficiencies?

NELAC 6.3.3.2(c) – Does the NELAP evaluation team send by certified mail an application technical review report to the accrediting authority?

NELAC 6.3.3.2(c) – Does this report identify any specific deficiencies noted during the application technical review, include references to the specific NELAC Standards, and provide suggested corrective action?

NELAC 6.3.3.2(d) – Does the NELAP evaluation team review any submitted corrective actions within 30 calendar days of receipt of the accrediting authority's response?

NELAC 6.3.3.2(d)(1) - If the corrective actions submitted by the accrediting authority do not meet the requirements of NELAC Chapter 6, does the NELAP evaluation team notify the accrediting authority that it must submit additional corrective actions within 20 calendar days of receipt of the NELAP evaluation team's response?

NELAC 6.3.3.2(d)(1) – Does the NELAP evaluation team review the accrediting authority's second corrective action response within 20 calendar days of receipt?

NELAC 6.3.3.2(d)(2) - If the second corrective action response submitted by the accrediting authority does not address satisfactorily all of the application deficiencies, does the NELAP evaluation team make no further suggestions to the accrediting authority for correction of application deficiencies?

NELAC 6.3.3.2(d)(3) - If application deficiencies still remain after the team's second attempt to resolve those deficiencies, does the NELAP evaluation team document those deficiencies which are not resolved and recommend to the NELAP Director that the accrediting authority's application for NELAP recognition be denied or revoked?

NELAC 6.3.3.2(e) - If the initial application as submitted contained no deficiencies, or if deficiencies were corrected (except any deficiencies requiring legislative or rulemaking action) does the NELAP evaluation team schedule the on-site assessment of the accrediting authority?

NELAC 6.3.3.2(g) - After review of the renewal NELAP-recognition application and supporting documents, does the NELAP evaluation team schedule, when required, an on-site assessment of the accrediting authority's environmental laboratory accreditation program?

ON-SITE ASSESSMENT OF THE ACCREDITING AUTHORITY

NELAC 6.4(a) – Does NELAP conduct on-site assessments of an accrediting authority's environmental laboratory accreditation program in conjunction with an accrediting authority's initial application process and at least every four years thereafter?

NELAC 6.4(b) – Does the NELAP evaluation team arrange on-site assessments at the mutual convenience of both parties?

NELAC 6.4(c) – Does the NELAP evaluation team make subsequent announced or unannounced on-site assessments of an accrediting authority's environmental laboratory accreditation program only whenever such an assessment is necessary to determine the accrediting authority's compliance with the requirements of the NELAC Standards?

NELAC 6.4.1(a) – Does the NELAP evaluation team contact the accrediting authority to schedule on-site assessment within 20 calendar days of the date that the team accepts an initial or renewal application?

NELAC 6.4.1(b) – Does the NELAP evaluation team send to the accrediting authority written confirmation of the logistics required to conduct the on-site assessment?

NELAC 6.4.1(b) – Does the written confirmation include:

- (1) on-site assessment date and agenda or schedule of activities,
- (2) copies of the standardized assessment checklists,
- (3) the names, titles, affiliations, and on-site assessment responsibilities of the NELAP evaluation team members, and,
- (4) the names and titles of all accrediting authority staff that need to be available during the on-site assessment?

NELAC 6.4.1(c) – Are the NELAP on-site assessments conducted no later than 50 calendar days following approval of the application?

NELAC 6.4.2(b) – During the on-site assessment, does the NELAP evaluation team, at a minimum:

- (1) review the accrediting authority's record keeping and documentation procedures;
- (2) conduct interviews with the accrediting authority's management and technical staff;
- (3) review selected laboratory accreditation cases;
- (4) review records of laboratory complaints, disputes and appeals; and,
- (5) review quality assurance and internal audit procedures employed by the accrediting authority?

NELAC 6.4.2(e) – Does the NELAP evaluation team ensure that the on-site assessment consists of opening meeting, a comprehensive on-site assessment of the accrediting authority's environmental laboratory accreditation program, and an exit interview to discuss all noted deficiencies?

NELAC 6.4.2(f) – Does the NELAP evaluation team shall conduct all assessments in accordance with the NELAP standard operating procedure for conducting on-site assessments of accrediting authorities?

NELAC 6.4.3(a) – Does the NELAP evaluation team send by certified mail to the accrediting authority an on-site assessment report within 30 calendar days of completion of the on-site assessment?

NELAC 6.4.3(a) – Does the report include:

- (1) the date(s) of assessment;
- (2) the name(s) of the person(s) responsible for the report;
- (3) the NELAP recognition fields of testing for which initial recognition or renewal is sought; and,

(4) the comments of the NELAP evaluation team on the accrediting authority's compliance with the requirements of the NELAC standards?

NELAC 6.4.3(b) - If the on-site assessment does not reveal any deficiencies, does the NELAP evaluation team recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP Recognition?

NELAC 6.4.3(c) - If deficiencies are noted during the on-site assessment, does the report identify any specific deficiencies noted during the on-site assessment, include references to the specific NELAC standards, and provide suggested corrective action?

NELAC 6.4.3(e) – Does the NELAP evaluation team recommend to the NELAP Director revocation or denial of NELAP recognition for on-site assessment deficiencies for any accrediting authority that fails to submit a plan of corrective action within 30 calendar days?

NELAC 6.4.3(f) – Does the NELAP evaluation team respond in writing to the accrediting authority within 20 calendar days of receipt of the accrediting authority's plan of corrective actions?

NELAC 6.4.3(f)(1) - If the accrediting authority corrects all deficiencies, does the NELAP evaluation team recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition?

NELAC 6.4.3(f)(2) - If the accrediting authority's plan of corrective actions does not address all deficiencies, does the NELAP evaluation team notify the accrediting authority by certified mail that it must submit another plan of corrective actions for the remaining deficiencies within 20 calendar days of the accrediting authority's receipt of this notification?

NELAC 6.4.3(g) – Does the NELAP evaluation team review the second submittal of corrective actions for the remaining deficiencies within 20 calendar days of receipt of the response from the accrediting authority?

NELAC 6.4.3(g)(1) - If all deficiencies are not corrected and the remaining deficiencies affect only certain fields of accreditation, does the NELAP evaluation team recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked for those fields of testing for which on-site assessment deficiencies remain?

NELAC 6.4.3(g)(2) - If all deficiencies are not corrected and the remaining deficiencies affect the entire accrediting authority's environmental laboratory accreditation program, does the NELAP evaluation team recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked?

NELAC 6.4.3(g)(3) - If the only remaining deficiencies require legislation or rulemaking, does the NELAP evaluation team shall to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition?

NELAC 6.4.3(g)(4) - If the remaining deficiencies are corrected, does the NELAP evaluation team recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition?

NELAC 6.4.3(h) - If the NELAP assessment team determines that the accrediting authority has falsified information included in its application and supporting documents, does the NELAP evaluation team recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked?

NELAP EVALUATION TEAM RECOMMENDATIONS TO THE NELAP DIRECTOR

NELAC 6.6(a) – Does the NELAP evaluation team make all recommendations required by NELAC Chapter 6 to the NELAP Director in writing?

NELAC 6.6(b) – Do all NELAP evaluation team recommendations to the NELAP Director include the following documentation when applicable:

- (1) a recommendation to grant, maintain or revoke NELAP recognition in full or in part;
- (2) a summary of the reasons supporting the recommendation;
- (3) a copy of all application review letters sent to the accrediting authority and all corrective action response letters submitted by the accrediting authority to the NELAP evaluation team;
- (4) a copy of all on-site assessment review letters sent to the accrediting authority and all corrective action response letters submitted by the accrediting authority;
- and,
- (5) a copy of the accrediting authority's requests for extension of time to implement corrective actions if legislative or additional rulemaking is required?

NELAC 6.6(c) – Does the NELAP evaluation team furnish to the accrediting authority a copy of its recommendation with all supporting documentation to the NELAP Director?

NELAC 6.6(d) - Within 20 calendar days of receipt of the NELAP evaluation team's recommendation, does the NELAP Director shall provide written notification to the accrediting authority of acceptance or rejection of the NELAP assessment team's recommendation?

NELAC 6.9(a) – Does the NELAP evaluation team submit all documents, letters, assessment notes, checklists, etc. to the NELAP headquarters office within 30 calendar days of the final decision on the application by the NELAP Director, or within 30 calendar days after any final recommendations by the Accrediting Authority Review Board?

NELAC 6.9(b) – Does the NELAP Director maintain complete and accurate records of all documents relating to the application and on-site assessment processes for each accrediting authority for a minimum of ten years, or a longer period of time if required by contractual obligations or pertinent federal laws and regulations?

NELAC 6.9(c) – Does the NELAP Director maintain an electronic directory to display the status of all NELAP-recognized accrediting authorities, pending applications for NELAP recognition, and currently scheduled announced on-site assessments?

CERTIFICATE OF RECOGNITION TO THE ACCREDITING AUTHORITY

NELAC 6.7(a) – Does the NELAP Director issue a certificate of NELAP recognition to the accrediting authority dated the day on which NELAP recognition is granted?

NELAC 6.7(b) – Does the certificate of NELAP recognition include the following items:

- (1) the name and address of the accrediting authority,
- (2) the fields of accreditation for which the accrediting authority is NELAP-recognized,
- (3) the date of the accrediting authority's most recent on-site assessment,
- (4) the expiration date of the accrediting authority's NELAP recognition, which shall not be more than two years from the date of the most recent date granting NELAP recognition,
- (5) the signature of the NELAP Director,
- (6) a statement that the accrediting authority is in compliance with the NELAC standards,
- (7) a statement that the accrediting authority has been granted the authority to accredit environmental laboratories for the fields of accreditation for which the accrediting authority is NELAP-recognized,
- (8) a statement that continued NELAP recognition depends on compliance with the NELAC standards;
- (9) a seal incorporating the NELAP insignia; and,
- (10) a unique designator, such as date of issuance and a serial or certificate number?

SUPPLEMENTAL REQUIREMENTS FOR NELAP SPECIFIED BY ISO Guide 61

Section 2: Requirements for Accreditation Bodies (NELAP in this case)

ISO 61: 2.1.1.1 - Does NELAP have policies & procedures so that it operates & is administered in a non-discriminatory manner? _____

ISO 61: 2.1.1.2 - Are NELAP services accessible to all federal & state environmental laboratory accrediting authority applicants? _____

ISO 61: 2.1.1.2 - Does NELAP not impose undue financial or other conditions on applicant accrediting authorities? _____

ISO 61: 2.1.1.2 - Does NELAP not impose conditions on applicant accrediting authorities based on their size or affiliation or number of accreditations bestowed? _____

ISO 61: 2.1.1.3 - Does NELAP assess Accrediting Authorities according to ISO Guide 62 or other relevant normative documents (e.g., NELAC Chapter 6)? _____

ISO 61: 2.1.1.3 - Has NELAP formulated explanations of applicability of ISO standards and NELAC Standards to NELAP and to accrediting authorities? _____

ISO 61: 2.1.1.4 - Does NELAP confine requirements, assessments, & decisions to the scope of recognition sought by accrediting authorities? _____

ISO 61: 2.1.2 - Is the NELAP structure such that it gives confidence in its recognitions of accrediting authorities? _____

Does the NELAP organization and structure ensure that:

ISO 61: 2.1.2(a) - NELAP is impartial? _____

ISO 61: 2.1.2(b) - NELAP is responsible for decisions relating to granting, maintaining, extending, reducing, suspending, or withdrawing recognitions? _____

ISO 61: 2.1.2(c) - NELAP has identified management with overall responsibility of the following? _____

- performance of assessment and accreditation,
- formulation of policy matters relating to its operation,
- decisions on accreditation,
- supervision of the implementation of its policies,
- delegation of authority to committees to undertake defined activities on its behalf, as required;

ISO 61: 2.1.2(d) - NELAP has documents that demonstrate that it is a legal entity? _____

- ISO 61: 2.1.2(e)** - NELAP has a documented structure that safeguards confidentiality and enables participation of all parties concerned in development of policies and principles regarding content and functioning of NELAP? _____
- ISO 61: 2.1.2(f)** - NELAP ensures that accreditation decisions are made by persons different from those carrying out the assessment? _____
- ISO 61: 2.1.2(g)** - NELAP has rights and responsibilities relevant to accreditation activities? _____
- ISO 61: 2.1.2(h)** - NELAP has adequate arrangements to cover liabilities arising from its operations? _____
- ISO 61: 2.1.2(i)** - NELAP has financial stability and resources required for operation of its accreditation system? _____
- ISO 61: 2.1.2(j)** - NELAP employs sufficient personnel with training, education, technical knowledge, and experience for performing accreditation functions under a responsible senior executive? _____
- ISO 61: 2.1.2(k)** - NELAP has a quality system giving confidence in its ability to operate the NELAP accreditation system? _____
- ISO 61: 2.1.2(l)** - NELAP has policies and procedures to distinguish among accreditations, recognitions, and any other activities in which it is engaged? _____
- ISO 61: 2.1.2(m)** - NELAP is free from commercial, financial, or other pressures that might influence the results of the accreditation or recognition process? _____
- ISO 61: 2.1.2(n)** - NELAP has formal rules and structures for the appointment of any committees involved with the accreditation or recognition process? _____
- ISO 61: 2.1.2(o)** - NELAP ensures that activities of the recognized Accrediting Authorities do not offer or provide: _____
- services that it accredits laboratories to perform,
 - consulting services to obtain or maintain accreditation,
 - service to design or implement a certification scheme
- ISO 61: 2.1.2(p)** - NELAP has policies and procedures for the resolution of complaints, appeals, and disputes about the handling of accreditation, recognition, or any related matters? _____
- ISO 61: 2.1.3** - Has NELAP made arrangements for subcontracting any of its accreditation or recognition functions, or else stated that it does not intend to subcontract its services to another party? _____

ISO 61: 2.1.4.1 - Does NELAP have a quality policy statement, which states its objectives & commitment to quality? _____

ISO 61: 2.1.4.2 - Does NELAP have a documented quality system? _____

ISO 61: 2.1.4.2 - Is the NELAP quality system available for use by all its staff and personnel? _____

ISO 61: 2.1.4.2 - Does NELAP have procedures to ensure effective implementation of its quality system? _____

ISO 61: 2.1.4.2 - Has NELAP appointed a person to establish & maintain its quality system and to report on its performance? _____

ISO 61: 2.1.4.3 - Does NELAP have a quality manual & associated quality procedures (SOP's) to document its quality system? _____

Does the NELAP quality manual contain the following:

ISO 61: 2.1.4.3(a) - Quality policy statement? _____

ISO 61: 2.1.4.3(b) - Brief description of legal status, including names of any applicable persons who control NELAP? _____

ISO 61: 2.1.4.3(c) - Names, qualifications, experience, and terms of reference for the senior executive and other personnel influencing the quality of the accreditation and recognition functions? _____

ISO 61: 2.1.4.3(d) - Organization chart showing lines of responsibility, allocation of functions from the senior executive, and relationship between those personnel making assessments and personnel making decisions regarding accreditations or recognitions? _____

ISO 61: 2.1.4.3(e) - Description of the NELAP organization, its management, constitution, terms of reference, and rules of procedure? _____

ISO 61: 2.1.4.3(f) - Policy and procedures for conducting management reviews? _____

ISO 61: 2.1.4.3(g) - Administrative procedures including document control? _____

ISO 61: 2.1.4.3(h) - Operational and functional duties and services related to quality, such that the extent and limit of each person's responsibilities are known to all? _____

ISO 61: 2.1.4.3(i) - Policies and procedures for recruiting and training personnel and monitoring their performance? _____

ISO 61: 2.1.4.3(j) - List of any subcontractors and details of procedures for assessing, monitoring, and recording their competence? _____

ISO 61: 2.1.4.3(k) - Procedures for handling nonconformities and assuring effectiveness of any corrective actions taken? _____

ISO 61: 2.1.4.3(l) - Policies and procedures for implementing the accreditation process that include: _____

- conditions for issue, retention, and withdrawal of accreditation documents,
- checks of the use and application of documents used in accreditation,
- procedures for assessing and accrediting applicants,
- procedures for surveillance and reassessment of Accrediting Authorities

ISO 61: 2.1.4.3(m) - Policy and procedures for dealing with complaints, appeals, and disputes? _____

ISO 61: 2.1.4.3(n) - Procedures for conducting internal audits? _____

ISO 61: 2.1.5.1 - Has NELAP documented its conditions for its accreditation and recognition decisions? _____

ISO 61: 2.1.5.1 - Has NELAP documented its notification requirements by accrediting authorities whenever their quality systems are revised or other changes affect conformity? _____

ISO 61: 2.1.5.2 - Has NELAP documented its procedures for accomplishing the above accreditation or recognition decisions or conducting re-evaluations when significant changes occur or complaints are received about an accrediting authority? _____

ISO 61: 2.1.6.1 - Has NELAP performed a periodic internal audit of its quality system? _____

ISO 61: 2.1.6.1 - Does NELAP document the results of the internal Audit of its quality system? _____

ISO 61: 2.1.6.1 - Does NELAP implmenet any needed corrective actions as a result of the internal audit? _____

ISO 61: 2.1.6.2 - Does NELAP perform a management review of its quality system at defined intervals? _____

ISO 61: 2.1.6.2 - Does NELAP maintain records of the management review of its quality system? _____

Does the NELAP documentation available for review include:

ISO 61: 2.1.7.1(a) - Information about the authority under which it operates? _____

- ISO 61: 2.1.7.1(b)** - Documented statements, rules, and procedures for granting, maintaining, extending, reducing, suspending, and withdrawing accreditations and recognitions? _____
- ISO 61: 2.1.7.1(c)** - Information about the assessment and accreditation/recognition process? _____
- ISO 61: 2.1.7.1(d)** - Description of how NELAP obtains financial support and any fees charged to Accrediting Authorities and applicants? _____
- ISO 61: 2.1.7.1(e)** - Description of the rights and duties of Accrediting Authorities and applicants, including any restrictions on the use of the NELAP logo or references to the accreditations or recognitions received? _____
- ISO 61: 2.1.7.1(f)** - Information on handling complaints, appeals, and disputes? _____
- ISO 61: 2.1.7.1(g)** - Directory of NELAP recognized Accrediting Authorities and NELAP accredited laboratories, showing their locations and scopes of accreditation granted to each? _____
- ISO 61: 2.1.7.2** - Has NELAP established procedures to control all documents and data relating to the accrediting authority recognition process? _____
- ISO 61: 2.1.7.2** - Does NELAP review and approve these documents for adequacy prior to issuance? _____
- ISO 61: 2.1.7.2** - Does NELAP maintain a listing of documents issued and their amendment status? _____
- ISO 61: 2.1.7.2** - Does NELAP control document distribution to ensure availability to NELAP personnel and accrediting authorities? _____
- ISO 61: 2.1.8.1** - Does NELAP maintain a record system of its accrediting authority recognition procedures (application forms, assessment reports, documents relating to granting, maintaining, extending, reducing, or withdrawing recognition status)? _____
- ISO 61: 2.1.8.1** - Does the NELAP record system demonstrate effective fulfillment of the accrediting authority recognition procedures? _____
- ISO 61: 2.1.8.1** - Are the NELAP records identified, managed, and disposed so as to ensure integrity of the recognition process and confidentiality? _____
- ISO 61: 2.1.8.1** - Are the NELAP records kept for at least one full accreditation/recognition cycle or longer if needed to demonstrate continued confidence? _____

ISO 61: 2.1.8.2 - Does NELAP have a policy & procedures for records access and for records retention consistent with any legal or contractual obligations? _____

ISO 61: 2.1.9.1 - Does NELAP have arrangements for safeguarding confidentiality? _____

ISO 61: 2.1.9.2 - Does NELAP inform the Accrediting Authority and get its written consent before disclosing its information to a third party? _____

ISO 61: 2.2.1.1 - Are all NELAP personnel competent for the functions they perform? _____

ISO 61: 2.2.1.2 - Does NELAP maintain up-to-date information on the qualifications, training, and experience of personnel involved in the accrediting authority recognition process? _____

ISO 61: 2.2.1.3 - Does NELAP provide clear up-to-date instructions to the accrediting authority evaluation personnel describing their duties & responsibilities? _____

ISO 61: 2.2.2.1 - Has NELAP defined the minimum relevant criteria for accrediting authority evaluator competence? _____

ISO 61: 2.2.2.2 - Do the NELAP accrediting authority evaluators meet the requirements of relevant international documentation? _____

ISO 61: 2.2.2.3 - Does NELAP employ qualified technical experts in the accrediting authority recognition process, or else state that outside technical experts are not employed? _____

ISO 61: 2.2.3.1(a) - Does NELAP have procedures for selecting accrediting authority evaluators on the basis of competence, training, experience, and qualifications? _____

ISO 61: 2.2.3.1(b) - Does NELAP assess the conduct of evaluators and monitor their on-going performance? _____

Does NELAP ensure that each accrediting authority evaluation team:

ISO 61: 2.2.3.2(a) - Is familiar with NELAP accrediting authority recognition procedures and requirements? _____

ISO 61: 2.2.3.2(b) - Has thorough knowledge of accrediting authority evaluation documents and methods? _____

ISO 61: 2.2.3.2(c) - Has appropriate technical knowledge of the activities for which NELAP recognition is sought (including associated procedures and potential for failure)? _____

ISO 61: 2.2.3.2(d) - Has understanding sufficient to make a reliable assessment of the competence of the accrediting authority to offer NELAP laboratory accreditations? _____

- ISO 61: 2.2.3.2(e)** - Communicates effectively in writing and orally? _____
- ISO 61: 2.2.3.2(f)** - Is free from conflict of interest that would compromise acting in impartial nondiscriminatory manners? _____
- ISO 61: 2.2.4** - Does NELAP require evaluators to sign a contract committing to comply with NELAP rules (including confidentiality, links to the accrediting authority to be assessed, and independence from commercial or other interests)? _____
- ISO 61: 2.2.5** - Does NELAP have up-to-date records on each evaluator's name and address, affiliation and position held, educational qualifications and professional status, experience and training in NELAP, date of most recent updating of the record, and performance appraisals? _____
- ISO 61: 2.2.6** - Does NELAP provide its evaluation teams with up-to-date instructions and relevant information on evaluation arrangements & procedures? _____
- ISO 61: 2.3.1** - Does NELAP base its accrediting authority recognition decision on information gathered during the evaluation process? _____
- ISO 61: 2.3.1** - Is the accrediting authority recognition decision made by personnel different than the evaluation team personnel? _____
- ISO 61: 2.3.2** - Does NELAP not delegate accrediting authority recognition decisions to an outside party? _____
- ISO 61: 2.3.3** - Does NELAP provide to accrediting authorities recognition certificates that contain: _____
- accrediting authority name and address;
 - scope of recognition granted (Fields of Accreditation);
 - effective date and term for which recognition status is valid
- ISO 61: 2.3.4** - Does NELAP have procedures appropriate to evaluate accrediting authorities when they apply to change their scope of recognition (i.e., Fields of Accreditation offered under NELAP)? _____
- ISO 61: 2.4.1** - Does NELAP have a policy governing use of the NELAP logo? _____
- ISO 61: 2.4.2** - Does NELAP not allow use of its logo as if to approve a product, service, or system and prevents any inference of the logo to product performance? _____
- ISO 61: 2.4.3** - Does NELAP take suitable actions to deal with incorrect references or misleading use of the logo or of accrediting authority recognition status? _____

- ISO 61: 2.5** - Does NELAP give accrediting authorities notice of any intended changes to recognition requirements? _____
- ISO 61: 2.5** - Does NELAP take account of accrediting authority opinions before deciding on the changes and effective dates of changes in recognition requirements? _____
- ISO 61: 2.5** - Does NELAP verify that accrediting authorities adjust their laboratory accreditation functions accordingly within a reasonable time? _____
- ISO 61: 2.6.1** - Does NELAP have procedures for any appeals, complaints, and disputes from accrediting authorities regarding recognition status? _____
- ISO 61: 2.6.2** - Does NELAP keep records of all such appeals, complaints, and disputes? _____
- ISO 61: 2.6.2** - Does NELAP take corrective and preventive action resulting from appeals, complaints, and disputes? _____
- ISO 61: 2.6.2** - Does NELAP document any corrective actions taken as a result of appeals, complaints, and disputes? _____
- ISO 61: 2.6.2** - Does NELAP monitor the effectiveness of any corrective actions arising from appeals, complaints, and disputes? _____
- ISO 61: 2.7** - Does NELAP requires accrediting authorities to make available records of all complaints, appeals, disputes, and subsequent actions brought to them by laboratories or other accrediting authorities? _____

Section 3: Technical Requirements for Evaluations

- ISO 61: 3.1.1.1.1** - Does NELAP have detailed description of the evaluation and recognition procedures, documents describing these procedures, and documents describing rights and duties of recognized accrediting authorities? _____
- ISO 61: 3.1.1.1.1** - Does NELAP provides this information on evaluation and recognition procedures to accrediting authorities? _____
- Does NELAP require that accrediting authorities:
- ISO 61: 3.1.1.2(a)** - comply with relevant sections of ISO Guide 61? _____
- ISO 61: 3.1.1.2(b)** - make arrangements for the evaluations, including examining accrediting authority documentation, access to all areas, records (e.g., internal audit reports), and personnel for purposes of assessment, surveillance, and resolution of complaints? _____

ISO 61: 3.1.1.2(c) - only claim recognition status for those Fields of Accreditation for which they are indeed Recognized? _____

ISO 61: 3.1.1.2(d) - not make misleading or unauthorized statements or use its recognition status in a way to bring NELAP into disrepute? _____

ISO 61: 3.1.1.2(e) - return all NELAP accrediting authority recognition documents and discontinue use of all advertising that references recognition status when its status is suspended or withdrawn? _____

ISO 61: 3.1.1.2(f) - not allow accrediting authorities to use recognition status to imply NELAP endorsement of its laboratory accreditation program (over another state's program)? _____

ISO 61: 3.1.1.2(g) - ensure no misleading usage of any NELAP issued certificates or reports? _____

ISO 61: 3.1.1.2(h) - comply with NELAP requirements associated with documents, brochures, or advertising? _____

ISO 61: 3.1.1.3 - Does NELAP provide explanations to accrediting authorities when recognition status relates to specific programs (i.e., SDWA, CWA)? _____

ISO 61: 3.1.1.4 - Does NELAP provide any additional application information if requested by accrediting authorities? _____

ISO 61: 3.1.2.1 - Does NELAP require a completed official application form signed by authorized representative of the Accrediting Authority? _____

ISO 61: 3.1.2.1 - Does the application define the scope of recognition desired by the accrediting authority? _____

ISO 61: 3.1.2.1 - Does the application contain statements that the accrediting authority agrees to comply with NELAP recognition requirements and supply any information needed for the application's evaluation? _____

Do the accrediting authorities provide NELAP the following information prior to the on-site assessment:

ISO 61: 3.1.2.2(a) - name, organization or affiliation, addresses, legal status, and relevant human and technical resources? _____

ISO 61: 3.1.2.2(b) - accrediting authority's functions, physical locations, and relationships within the larger organization? _____

ISO 61: 3.1.2.2(c) - description of the laboratory accreditations it offers, plus the standards or regulations applicable to each? _____

ISO 61: 3.1.2.2(d) - copy of accrediting authority's quality manual and any required associated documentation? _____

ISO 61: 3.2.1 - Does NELAP review (and maintain records of such reviews) the accrediting authority's recognition requests to ensure that: _____

- AA recognition requirements are clearly defined
- any differences between NELAP and the AA are resolved
- NELAP has the ability to perform the recognition process with respect to the AA's recognition requests, physical location, and any special requirements

ISO 61: 3.2.2 - Does NELAP have a prepared plan for its assessment activities to allow arrangements to be made? _____

ISO 61: 3.2.3 - Does NELAP nominates a qualified assessment team to evaluate submitted information from the accrediting authorities and to conduct evaluations on its behalf? _____

ISO 61: 3.2.4 - Are accrediting authorities informed of the evaluation team members and given sufficient notice for appealing against any particular appointments? _____

ISO 61: 3.2.5 - Does NELAP formally appoint the accrediting authority evaluation team and provide it with appropriate working documents? _____

ISO 61: 3.2.5 - Does NELAP ensure that the plan for and date of the evaluation is agreed upon with the accrediting authority? _____

ISO 61: 3.2.5 - Does NELAP clearly define its mandate to the evaluation team and made this mandate known to the accrediting authority? _____

ISO 61: 3.2.5 - Does NELAP require the evaluation team to assess the accrediting authority's structure, policy & procedures, to confirm compliance with NELAP requirements with respect to the scope of recognition sought, and to confirm the accrediting authority's implementation of procedures so as to give confidence in the NELAP accreditations bestowed to laboratories? _____

ISO 61: 3.3.1 - Do the NELAP evaluation teams assess all accrediting authority services covered by the defined scope against NELAP's requirements for recognition? _____

ISO 61: 3.3.2 - Do the NELAP evaluation teams fully witness the on-site assessment activities of the accrediting authority on 1-2 laboratories before NELAP recognition

is bestowed to the accrediting authority? _____

Do NELAP's accrediting authority evaluation reporting procedures ensure that:

ISO 61: 3.4.1(a) - a meeting occurs between the evaluation team and the accrediting authority's management prior to leaving the premises, at which the team provides indication of the accrediting authority's conformity to NELAP recognition requirements and at which the accrediting authority can ask questions about the findings and their bases? _____

ISO 61: 3.4.1(b) - the evaluation team gives the accrediting authority a report of the findings as to the accrediting authority's conformity with NELAP's recognition requirements? _____

ISO 61: 3.4.1(c) - this report is issued promptly to the accrediting authority and identifies any nonconformities to be corrected in order to comply with NELAP's accrediting authority recognition requirements? _____

ISO 61: 3.4.1(d) - NELAP invites the accrediting authority to comment on the report and to describe the actions taken or planned to remedy any nonconformities with NELAP's recognition requirements identified during the evaluation, and NELAP informs the accrediting authority as to whether a full or partial re-evaluation or written declaration to be confirmed during surveillance is needed? _____

ISO 61: 3.4.1(e) - the report contains the dates of the evaluation, names of the personnel responsible for the report, names and addresses of all sites evaluated, the assessed scope of NELAP recognition, comments on the accrediting authority's conformity with the NELAP recognition requirements (and any comparisons with the results of previous evaluations of the accrediting authority where applicable), and explanations of any differences in the information presented to the accrediting authority at the closing meeting? _____

ISO 61: 3.4.2 - If the final report from NELAP to the accrediting authority differs from the evaluation team's report, does the NELAP final report explain any differences from the evaluation team report and take into consideration: _____

- qualifications, experience, and authority of the staff encountered
- adequacy of the accrediting authority's internal organization and procedures to give confidence in the quality of its NELAP accreditations bestowed to laboratories
- actions the AA has taken to correct identified nonconformities (including those nonconformities identified during previous evaluations)

ISO 61: 3.5.1 - Does NELAP have an established documented program for carrying out periodic re-evaluations of accrediting authorities at sufficiently close intervals to verify that accrediting authorities continue to comply with NELAP recognition requirements?

ISO 61: 3.5.2 - Are NELAP's re-evaluation procedures of accrediting authorities consistent with the initial evaluation procedures?

ISO 61: 3.5.3 - Does NELAP have arrangements to ensure that the accrediting authority informs NELAP without delay of any changes in its operations that affect its legal or organizational status, organization and management, policies and procedures where appropriate, premises, and personnel, equipment, facilities, working environment, or other resources where significant?

ISO 61: 3.5.3 - Does NELAP have arrangements to ensure that the accrediting authority informs NELAP of any other matters that may affect its capability, scope of recognized activities, or conformance with NELAP's recognition requirements?

<end>